K093022

510(K) SUMMARY

JAN 20 2010

11.1 SUBMITTER INFORMATION

A.	Company Name:	Access Scientific, Inc.
B.	Company Address:	12526 High Bluff Drive, Suite 360 San Diego, CA 92130
C.	Company Phone:	(858) 259-8333
D.	Company Facsimile:	(858) 259-5298
E.	Contact Person:	Albert Misajon Vice President, Regulatory Affairs and Quality Assurance amisajon@the-wand.com

11.2 DEVICE IDENTIFICATION

A.	Device Trade Name:	the PICC WAND® Peelable Safety Introducer
B.	Common Name:	Catheter Introducer
C.	Classification Name(s):	Introducer, Catheter
D.	Classification Regulation(s):	21 CFR 870.1340
E.	Device Class:	Class II
F.	Product Code:	DYB
G.	Advisory Panel:	Cardiovascular

11.3 IDENTIFICATION OF PREDICATE DEVICE

The PICC WAND® Peelable Safety Introducer is substantially equivalent to the WAND® MicroAccess Safety Introducer manufactured by Access Scientific, Inc. and cleared for commercial distribution under 510(k) K090372.

11.4 DEVICE DESCRIPTION

The PICC WAND® Peelable Safety Introducer is an integrated sterile, single-use intravascular catheter introducer. It is designed to incorporate a combination of devices into an all-in-one device that provides the clinician with a safe and simple approach to the Modified Seldinger technique, and thereby accelerate the procedure required to place in-dwelling intravascular catheters. The device includes an Introducer Needle, Guidewire, Dilator, and a Peelable Sheath Introducer in a single integrated device, and incorporates a safety mechanism to guard against accidental needlestick.

11.5 INDICATIONS FOR USE

The PICC WAND® Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

11.6 BIOCOMPATIBILITY AND PERFORMANCE TESTING

A program of design verification testing including biocompatibility testing and *in vitro* bench testing has been completed to demonstrate the biological safety and biomechanical performance characteristics of the PICC WAND® Peelable Safety Introducer. Test results indicate that the device is equivalent to the predicate device and satisfies mechanical performance requirements for its intended use.

11.7 STERILITY

The PICC WAND® Peelable Safety Introducer is provided 'STERILE' by ethylene oxide gas to a sterility assurance level of 10^{-6}.

11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the PICC WAND® Peelable Safety Introducer is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 20 2010

Access Scientific, Inc
c/o Mr. Albert Misajon
Vice President, Regulatory Affairs and Quality Assurance
12526 High Bluff Drive, Ste 360
San Diego, CA 92130

Re: K093022
Trade Name: PICC WAND Peelable Safety Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: December 15, 2009
Received: December 16, 2009

Dear Mr. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093022

Device Name: **the PICC WAND® Peelable Safety Introducer**

Indications for Use:

The PICC WAND® Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093022